US ERA ARCHIVE DOCUMENT

TECHNICAL SUPPORT EFFICACY REVIEW - \boldsymbol{I}

Disinfectants Branch

IN 07-03-78 OUT 03-26-79
Reviewed by Dennis G. Guse Date 03-26-79
EPA Reg. No. or File Symbol 34292-1
EPA Petition or EUP No.
Date Division Received 03-02-78
Type Product(s):I, (D), H, (F), N, R, S Industrial Antimicrobial
Data Accession No(s). 233247
Product Mgr. No. 31 (Lee)
Product Name(s) DC 5700 Antimicrobial Agent
Company Name(s) Dow Corning Corporation
Submission Purpose Additional data "in support of all pending
amended registrations"
Chemical & Formulation Technical chemical for
manufacturing use
Active Ingredient(s):
3-(Trimethoxysilyl)-propyldimethyl-octadecyl
ammonium chloride42

200.0 Introduction

200.1 Use(s):

The product is registered as a bacteriostat, algistat, and fungistat for manufacturing use as a preservative for unfinished textile fibers, fabrics, and threads.

Claims have also been accepted for its use in a finished article, socks, to prevent deterioration and discoloration caused by fungi and to inhibit odor causing bacteria.

The current submission is intended "in support of all pending amended registrations." No specific claim(s) and pattern(s) of use are proposed or described.

201.0 Data Summary

201.1.1 Brief Description of Tests:

- (A) "Identification of Bacteria Isolated from the Axillary Region of the Human Body." Reference: E-3069-D, dated 2-21-78.
- (B) "Antibacterial Activity of Apparel Fabric Treated with Dow Corning 5700 Antimicrobial Agent." E-3069-E, dated 2-21-78.

The above data are under Accession No. 233247.

201.1.2 Data Summaries:

See attached reports.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II Disinfectants Branch

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Product Manager No31 (Lee)
Product Name DC 5700 Antimicrobial Agent
Company Name Dow Corning Corporation

202.0 Recommendations

- (A) The submitted test data are adequate only to support the intrinsic value of the product as a bacteriostatic treatment for manufacturing use in the impregnation of textile fabrics. The tests did not address the criteria necessary to evaluate claims for specific end-uses of the product in finished textile articles or items. No attempt was made to demonstrate the microbiological problem in untreated apparel fabric (e.g. production of bacterial-caused odor).
- (B) If the treatment is intended to control microorganisms not related to human health (e.g. odorcausing bacteria) in wearing apparel, the claim must
 so specify and supporting efficacy data will not be
 required. However, the pesticidal problem which is the
 basis for the claim and treatment must be known or
 documented to exist for the intended pattern of use.
 Sufficient information as to the specific pattern of
 use must be provided, as well as adequate and complete
 directions for the end-use.
- (C) If the treatment is intended to control infectious microorganisms related to human health, the claim must so specify and supporting efficacy for the specific enduses will be required. For claims against infectious disease organisms, the treatment must provide elimination or significant reduction in numbers of target pathogens. When such claims involve highly critical patient care environments (operating suites, intensive care wards) only elimination of target infectious organisms, on/in the treated items (i.e., sterilization, disinfection) can be considered. A level of effectiveness providing only inhibition of bacterial growth (bacteriostasis) cannot be considered in situations where a human health hazard may exist.
- (D) Clarification, as indicated above, is required for any proposed additional claims for the product in the treatment of end-use articles or items.